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Can Generic Contraceptive Manufacturers Increase Equity Without Compromising Quality?

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Generic Drugs: Definitions

- **Broad definition:**
 - A copy (branded or not) of an existing original pharmaceutical formulation
- **US FDA standards:**
 - Pharmaceutically equivalent
 - Bioequivalent
 - Approved as safe and effective
 - Manufactured in Compliance with GMP
 - Adequately labeled
- **Other countries with similar standards:**
 - EU, Canada, Australia, Japan, Brazil

Can Generic Suppliers Increase Equity?

- Generic manufacturers increase the affordability of the drug supply (CBO 1995)
- Generic contraceptives tend to be cheaper than R&D originator brands (IMS 2006, PSP 2006)
- Procurement agencies and governments can get better prices by switching to generic suppliers (PSP-One 2006, RHSC 2006)
- Generic manufacturers have high volume/low margin business model that maximizes equity (Prahalad 2004)

Quality/Safety Issues

- Truly bioequivalent generic contraceptives are mostly manufactured for developed markets
- Manufacturers in developing countries tend to make products that are only pharmaceutically equivalent
- Enforcement of Good Manufacturing Practices (GMP) varies widely around the world
- Drugs destined for export may be subject to fewer regulatory controls (India)
- History of quality/safety issues in contraceptive manufacturing in China, India and Egypt

What Are the Risks?

- Health-related: Method failure
- Economic: Favoring equity at the expense of quality is counter productive (ARV experience)
- Ethical: Non-observance of GMP may be hazardous to workers
- Behavioral: Consumer trust is essential in building demand for contraceptive methods

Selecting “Safe” Suppliers

- Few Southern-based suppliers have earned the trust of donors and procurement agencies
- No consensus on assessing the quality of contraceptives made in developing countries
- WHO supplier pre-qualification will help but does not guarantee quality or safety
- Most procurement organizations are currently doing their own assessments (costly, time-consuming)
- Equity gains must be balanced with the costs of ensuring quality